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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,507	11/07/2003	Jacques Degelaen	Neogen 4.1-48	8535

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/702,507	DEGELAEN ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,26-32 and 34-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,26-32 and 34-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment dated 28 December 2006 has been received. Claims 24, 26-32 and 34-40 are pending.

2. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims and/or arguments.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 24, 26-32 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markovsky et al (US 6,319,466) in view of Joris (*FEMS Microbiology Letters*. Vol. 70. No. 1. 15 June 1990. Pages 107-113) and Litman et al (EP 0 093 613).

Markovsky discloses a device comprising a labeled receptor positioned within or proximate to a membrane. The membrane comprises a test zone having an analyte conjugate immobilized thereto to bind unbound receptor to form a first analyte conjugate receptor complex. The membrane further comprising a control zone including a binder immobilized thereto. See column 1, lines 52-67. Markovsky teaches that the receptor may bind a family of analytes which have similar structural binding sites. Markovsky also discloses a sample absorbing and a mobile-phase support zone

acting as a filter for somatic cells. See column 9, lines 7-14. The mobile-phase support zone is preferably Porex® pad or Porex® Lateral Flow Media. See column 10, lines 25-29. The device is configure to detect analytes such as beta lactams antibiotics in milk samples. See column 5, lines 11-20. The entire device is provided in a blister package including a removable seal strip at one end for application of the sample. See column 4, lines 8-20. Markovsky teaches that competitive assays for beta-lactams in milk sample can be done in 2 to 15 minutes. See column 3, lines 26-32. Markovsky teaches that test kits for detecting beta-lactams in biological fluids are well known in the art. See column 1.

Markovsky differs from the invention in failing to teach receptors obtained from *Bacillus lichenformis* as the labeled reagent. Markovsky also fail to teach a reference that is independent of the analyte.

Joris, however, discloses BLAR and BLAR-CTD involved in β-lactamase inducibility in *Bacillus lichenformis*.

And, Litman discloses a method and device for detecting an analyte comprising a measurement surface and a calibration surface binding to a reagent independent from the analyte. See page 4, lines 24-37.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the receptors taught by Joris in the device of Markovsky because Markovsky teaches that their device can be modified for the detection of a variety of analytes using appropriate reagents. See column 13, lines 23-39. Since Joris

discloses that receptors of as BLAR and BLAR-CTD are readily available are and well known in the art as having β-lactamase activity, a skilled artisan would have had a reasonable expectation of success in choosing the appropriate reagents for a particular analyte as taught by Markovsky.

Even though Markovsky does not specifically teaches that the mobile-phase support zone (i.e. purification membrane) retains leukocytes, Markovsky teaches that this zone is capable of filtering somatic cells, therefore, a skilled artisan would have had a reasonable expectation of success that such a membrane is capable of retaining leukocytes.

The use of an independent reference or calibration reagent is well known in the art and a skill artisan would have been motivated to use the calibration method and reagents taught by Litman in the device of Markovsky because Markovsky teaches a control comprising a broad spectrum antibody that is captured at the reference zone regardless of the presence or absence of an analyte in a sample and Litman teaches that it is advantageous to use a reagent that is independent from the analyte to provide a calibration or reference signal such that a standard for evaluation of the analyte at the detection zone can be obtained.

5. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markovsky in view of Joris and Litman as applied to claim 24 above, and further in view of Pall et al (US 6,074,869).

See the discussion of Markovsky, Joris and Litman above. These references differ from the instant invention in failing to specifically disclose the pore size of the purification membrane.

Pall, however, teaches membranes for filtering biological samples, including leukocytes and milk sample. See column 6, lines 32-62. Pall teaches that their membrane is a non-woven web and having an average pore size of 3 to 8μm. See column 8, lines 54-60.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the purification membrane taught by Pall in the device of Markovsky as modified by Joris because such a membrane is well known in the art and provides the advantage of a substantially uniform porous medium that can separate large somatic cells from a biological sample.

Response to Arguments

6. Applicant's arguments filed 28 December 2006 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Markovsky differs from the instant claims because Markovsky discloses using support 33 as a "secondary filter" underneath the sponge 32 to remove "somatic cells" in the sample assay. This construction is different than the instant primary purification membrane.

This argument is not persuasive. The instant claims uses the open "comprising" language, therefore, it does not exclude other components to be present. The fact that Markovsky call their filter a "secondary filter" does not change the function of the filter, mainly, that it is capable of retaining leukocytes.

The argument that Markovsky fails to disclose the use of BlaR or BlaR-CTA is not persuasive. Markovsky discloses the detection of antibiotic substances in milk samples. Joris discloses BLAR and BLAR-CTD involved in β-lactamase inducibility in *Bacillus lichenformis*. Since Joris discloses that receptors such as BLAR and BLAR-CTD are readily available are and well known in the art as having β-lactamase activity, a skilled artisan would have had a reasonable expectation of success in choosing the appropriate reagents for a particular analyte as taught by Markovsky.

The argument that one skilled in the art would have no basis for suggesting that the Pall fibrous web could be used in an assay kit for dairy products with BlaR or BlaR-CTD antibiotic binding proteins is not persuasive.

Markovsky discloses the detection of antibiotics in milk samples. Joris discloses BlaR and BlaR-CTD as well-known receptors for beta lactams such as those found in the milk samples of Markovsky. Markovsky also discloses filters for retaining somatic cells

from the milk samples and suggests membranes such as those available through Porex. Markovsky is silent with respect to the pore sizes of the Porex membranes. Pall, however, discloses Porex membranes and their pore sizes. Pall also discloses that Porex membranes are highly desirable for use in filtering leukocytes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Porex membranes having appropriate pore sizes in the device of Markovsky.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571)

272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 2/27/07